

POLICIES AND GUIDELINES
TECHNOLOGY TRANSFER PROGRAM

Patent and Invention Policy

I. Preamble

Patentable discoveries or inventions occasionally result from research or educational activities performed at a university. The Uniformed Services University of the Health Sciences (USUHS) desires to assure that all ideas and discoveries are properly disclosed and utilized for the greatest possible public benefit. The University also desires to protect the patent rights of the USUHS faculty, staff and student body, and to abide by patent regulations of agencies providing funds for sponsored programs. The following paragraphs present to the members of the USUHS Community the University's policy on patents, inventions and discoveries.

II. Coverage

The Uniformed Services University of the Health Sciences Patent Policy applies to all faculty, administrators, staff, students or other individuals who provided contracted services to the University or who use University facilities or materials in the process of conceiving an idea, invention or discovery.

All faculty and research staff are required, as a condition of their employment, to assign to the University their right to patents, inventions and discoveries which result from the performance of their duties. Additionally, students engaged in research supported by federal funds, and students receiving payment by the University while engaged in research are also required to assign the right to inventions and discoveries made in performance of their research.

III. Administration

The administration of this Patent Policy will reside in the office of the Director for Technology Transfer.

A Patents and Technology Review Committee shall be appointed by the President of the University or his designate and will include five to seven faculty and seven ex-officio members, with the Center for Technology Transfer-Director (CTT-Director) an ex-officio member as chair. The Committee shall meet periodically upon call of the Chair to review existing patent policy, to recommend any desired changes and to receive reports on the status of the patent portfolio. The CTT or designee will present periodic reports on the status of invention disclosures and patent applications to the Committee for their review. When necessary, the Committee shall meet with the Director (CTT) or representative if an inventor asks the Director (CTT) for a review by the Patent and Technology Review Committee of decisions relating to, or policies affecting, his invention or discovery. The Patent and Technology Review Committee shall normally report its decisions to the USUHS President through the Director (CTT).

V. Disclosure

All members of the USUHS Community who are covered by this policy shall disclose, on the USUHS Invention Disclosure Form, the nature and detail of their invention or discovery to the Director (CTT) or his designated representative.

Within 120 days after such disclosure the Director (CTT) or his designate shall notify the inventor in writing whether or not it is the University's intention to retain its interest and to acquire assignment of all ownership rights to the invention or discovery. If such notification cannot be made during that time period, the inventor shall be notified as to the reason for the delay and the additional time necessary to make such determination by the University. The principles to be used in determining ownership rights are given in Section VI.

VI. Ownership Rights

A. Ownership Rights in the University

All inventions or discoveries shall be deemed of proprietary interest to USUHS if the inventor was employed or otherwise financially supported by the University or if he used University facilities, materials or time to conceive and develop the discovery or invention.

If the University decides not to request assignment of ownership rights, and there are no restrictions by the sponsor of the research, the University may release its proprietary interest to the inventor. Notification of such release will normally be made within 120 days of disclosure.

B. No Ownership Rights in the University

The ownership rights to a discovery or invention are considered to be exclusive property of the inventor if the University has contributed nothing substantial or essential to the conception or development of the discovery or invention in the way of funds, space, materials or facilities and the discovery or invention was conceived and developed by the inventor on his own time. Members of the USUHS Community must be, careful to avoid situations which would be considered conflicts of interest when entering into agreements for consulting or providing of services outside of the University which require the member to assign his ownership rights to the contracting party. The Dean (SOM), the Vice President for Executive Affairs and the Director (CTT) should be notified of any patents or inventions arising from such consulting agreements.

C. Determination of Ownership Rights

In cases where there is a disagreement between the inventor and the University as to ownership rights or the retention of such rights by the University, the Director shall notify the inventor. The inventor shall be informed by the Director of the Procedures for requesting a formal Determination of Invention Rights.

D. Ownership Rights in Sponsored Programs

In the case of programs sponsored by government agencies or private firms with which the University has negotiated a particular agreement regulating patents, inventions, licensing, etc., the regulations of that agreement will govern. For all federal agencies with which there is no such agreement, the University agrees to provide an irrevocable non-exclusive paid-up license to the Government for the worldwide use, for Government purposes, of patents arising from programs which they supported.

VII Obtaining A Patent

If the rights to an invention or discovery are determined to belong to the University, the Director (CTT) will determine the desirability of acquiring assignment of such rights and filing for domestic (U.S.) or foreign patents. If the University decides to obtain a patent, one of the following alternatives, **will be pursued**:

- A. Patent Management Organization (such as The Jackson Foundation) will be designated by the University. The Patent Management Organization will provide patent, marketing and licensing services pursuant to an agreement with the University. However, the ownership right of the invention and any patent obtained thereupon shall still reside with the University and the division of any proceeds shall be in accord with general University policy on patents given in Section X; or
- B. The University will provide the patent filing services as well as the services of patent development and marketing and licensing services, at the University's own expense.

In the event the University determines that it is not interested in filing for a patent, or if the University decides to terminate the application for a patent after initiating the application process, the inventor shall be notified as is noted in Section V and he may proceed to obtain his own patent, at his own expense.

VIII. Inventions or Discoveries Arising From Sponsored Programs

The University will manage/coordinate the review of the rules and regulations of potential sponsors of research with regard to ownership rights and licensing of inventions, discoveries or patents either at the time that a proposal is submitted or prior to accepting an award from the sponsor. The University will facilitate this review with the following principles in mind:

- A. The project director/Principal Investigator is to have complete freedom to publish the results arising from the sponsored program;
- B. Any inventions, discoveries or patents arising from, the program will be used in the public interest;
- C. The University shall retain ownership rights in any inventions, discoveries or patents arising from the sponsored project and;
- D. All parties involved in the program, including the inventor, the sponsor, the University and patent management organization (if applicable) shall receive equitable compensation from any proceeds received from a patent or invention.

If, even after negotiation, the regulations of a potential sponsor are contrary to the University Patent Policy, the Director (CTT) **will consult with** the potential project director/Principal Investigator and University Vice President for Research and, if the Director (CTT) deems it advisable with the Patent and Technology Review Committee. After such consultation, the Director (CTT) will determine whether or not to accept the sponsorship of the research under those regulations.

IX. Development, Promotion and Licensing

In administering the patent portfolio of the University, the Director (Center for Technology Transfer) shall act to bring to the public the inventions and discoveries in which the University has proprietary rights. In doing this he shall use whatever means seem best for appropriate development, promotion and licensing of each invention, consistent with the expressed goals of the Patent Policy.

The University is free to enter into agreements with any outside agent which it feels will successfully aid the University in developing inventions or discoveries, in obtaining patents, or in promoting or manufacturing inventions, provided that such agreements are consistent with this Patent Policy. If a particular invention or discovery is to become subject to such an agreement, this shall be made known to the inventor, who will also be notified about any rules governing the relationship among the outside agent, the University and the inventor due to such agreement. The University is free to enter into any licensing agreements which it deems are beneficial to the University, the inventor and the public in general, provided such agreements are not prohibited by a sponsoring agency's rules or regulations. Any terms governing the relationship among the licensee, the University or the inventor due to such licensing agreements shall be disclosed to the inventor.

X. Proceeds From Inventions And Discoveries

All net income royalties or other payments which the University derives from the licensing of inventions and discoveries will be appropriately used for the research, educational functions, and technology transfer program of the University. The first \$2000.00 times the number of inventor(s) plus 20% of the balance (up to a total amount of \$150,000.00* annually per inventor) shall be distributed each year to the sole-inventor or shared among the joint-inventors equally. This income will be paid to the inventor(s), personally. The remaining approximately 80% will accrue to the University, with research funding, employee incentives, education/training, activities that increase the potential for transfer of the technology, and expenses incidental to the administration and licensing of intellectual property as the main goals for use of these funds. The university or patent management organization shall deduct its expenses incidental to the administration and licensing of intellectual property. Of the net proceeds, the distribution shall be as follows:

- 10% to the Office of the President;
- 10% to the Office of the Dean(SOM);
- 10% to the Center for Technology Transfer;
- 5% to the Chair of Sole-Inventor's Laboratory or shared equally among the chair(s) of the Joint-Inventor's Laboratories for departmental use
- 45% to the inventor's Laboratory

These royalties or other payments may be used or obligated only during the fiscal year in which they are received or during the succeeding fiscal year. All funds not expended within this period shall be paid into the U.S. Treasury.

- **Approval by the President of the United States is required to increase the \$150,000.00 limit.**

XI. Release of Patent Rights

The University, at its discretion and subject only to the restrictions of a sponsoring agency or a licensing agreement may release a previously obtained patent or pending patent application to the inventor for promotion and development. In so doing the University will require that it recover any costs incurred in obtaining the, patent or in subsequent promotions, and a non-exclusive, royalty-free and irrevocable license to use for Government purposes.

XII. Applicability of Policy

The policy herein declared may be changed or discontinued at anytime appropriately taken action of the President of the University. Such changes or discontinuance shall not affect the rights accrued prior to the changes or alterations.

Guide to Intellectual Property

Introduction

This guide to intellectual property for USUHS investigators offers basic information on protecting innovative ideas resulting from research and other educational activities. Emphasis is placed on patent and copyright protection, and the handling of biological materials, computer software, and know-how. The policies and procedures described in this guide reflect the University's practice of preserving traditional rights to disseminate research results, while at the same time providing a basis for protecting creative ideas.

Transfer of innovative ideas from the laboratory to the marketplace is a complex endeavor that depends on the close cooperation of individuals and institutions. Companies capable of developing, producing, and marketing innovative products or processes usually require that ideas are protected by patents or other means before risking the investment required to support development, manufacturing, marketing and sales costs. However, without intellectual property protection of one kind or another there would be little incentive for industry to commercialize important innovations.

When an invention is commercialized under license to a company, a number of benefits may flow to the inventor, the laboratory, and the university. These can include royalty income, research support, gifts or loans of scientific equipment, and consulting arrangements, not to mention unique opportunities for collaboration.

The Technology Transfer Program.

The Center for Technology Transfer (CTT), which is part of the Office of the Vice President for Executive Affairs, is responsible for implementing the Patent and Invention Policy for USUHS, and managing the transfer of technology from the University to industry.

The Director of the Center for Technology Transfer establishes policy, manages the technology transfer program and provides advice to the President regarding intellectual property policy issues.

CTT is responsible for managing USUHS inventions, and other intellectual properties. The goals of the program are to

- assist USUHS researchers in disseminating new and useful knowledge for the benefit of the public;
- promote the transfer of technology to industry through licensing and other commercial agreements;
- protect the inventor's interests and the University's ownership rights in intellectual property.
- distribute royalty and other income to the inventor, their department, the University, and other parties involved; and
- support technology transfer activities at the University from income derived from license activities.

Disclosing Inventions

Principal investigators and researchers are encouraged to report (disclose) to CTT their discoveries or inventions that arise from research conducted with USUHS University resources or using University facilities. The CTT office is ready for discussions with the researchers to identify such discoveries or inventions. An Invention Disclosure form, available at CTT and from our WebPages in fillable form, should be completed and returned along with a detailed description of the invention and with signatures of all inventors. On the basis of the disclosure, patenting or other means of protection will be explored. The University's patent policy requires researchers to assign their rights to all such inventions to the University.

It is important to disclose inventions to CTT before any public disclosure is made of the invention. Patent laws vary widely from country to country with respect to patentability after disclosure. In the United States, patents may be applied for no later than one year after the invention is described in a "printed publication," which includes manuscripts, abstracts distributed at conferences, oral presentation with printed viewgraphs or slides, or written notes disseminated during a presentation. The date of publication in a journal or an abstract for a conference is typically the mailing date of the journal (not the submission date) or the abstract books, or when the article is in print and made available through the internet. It should be noted that European patent rights are lost immediately upon either the written or oral disclosure of the invention.

The Invention Disclosure form is submitted once an inventive concept can be fully and precisely described, even if a physical embodiment of the idea has not been realized. If the invention meets patent law requirements and appears to be commercially attractive, a patent application may be filed before actual reduction to practice.

In addition to including a precise description of the invention on the disclosure form, investigators should take special care to name all others who have made a creative contribution to the inventive concept, including inventors at other, government agencies institutions or sponsoring organizations. Individuals who carried out work at the direction of those creating the concept ordinarily would not be designated as inventors. The naming of inventors on a patent, however, is a legal determination made with the aid of patent Counsel. It should be noted that all issues surrounding intellectual property and its protection are complex and should be reviewed with CTT professionals.

Reporting Inventions to Research Sponsors

CTT is required to report all inventions to sponsors, whether public or private. Certain rights to inventions vary according to the specific terms and conditions of the research agreements, and it is the responsibility of CTT to manage relevant issues so that conflicting interests, if they occur, are resolved.

When the sponsor is another agency of the U.S. government, federal law grants the University the right to, commercialize technology subject to certain conditions. If the University is unable to arrange suitable commercial agreements with industry, or decides not to pursue developing the technology for commercialization by other means, rights revert to the sponsoring government agency. The agency, in turn, may choose to make the invention public or otherwise dispose of ownership rights to the inventors. When an invention is the result of corporate funds, it is the obligation of the University to report such invention to the corporate sponsor.

Promoting Inventions to Industry

After CTT has received an invention disclosure, and after consultation with the inventor, nonconfidential material is prepared for distribution to selected companies or pertinent industry representatives who have particular market expertise.

Technical details of an invention may be disclosed to interested parties under a confidential disclosure agreement. Based on a company's further evaluation of the invention, which often involves direct communication with the inventor, a licensee may be identified and a license agreement may be negotiated. When further University research is needed to determine the merit of the invention, a research agreement with an option to license may be appropriate. If the response from industry is unfavorable, CTT will re-evaluate the invention and seek other opportunities. The commercial attractiveness of an innovative idea is determined by two considerations:

1. The idea must be protectable (e.g., by valid patents), so the company taking the risk and expense of development, seeking regulatory approval, and/or marketing, can control its use (and sale) for the life of the patents or long enough to receive a return on investment.
2. The idea must appeal to a potential market that is large enough to justify investment in development, manufacture, and marketing.

If a company is interested in an invention and a commercial agreement is anticipated, CTT will proceed to obtain patents or other forms of legal protection to protect the inventor's and the University's ownership rights. Due to the high costs associated with patent procedures, especially foreign patenting, CTT will seek to transfer patent costs to research sponsors or licensees. Marketability tends to be a prime factor in determining if patent protection will be pursued.

Distribution of Income

Licenses for commercial purposes may generate royalty or other income. The Patent and Invention Policy provides the formula for a division of net royalties between inventors and the University. Under current Department of Defense policy, of net proceeds are paid as stated in section X. Direct expenses if (applicable) related, to the invention (patentability search, patent, application fees, lawyers fees, and other out-of-pocket expenses) are deducted from gross revenue derived from the invention prior to distribution of the net income. CTT is responsible for all invention accounts.

Inventions and Patents

An invention is a novel and useful idea resulting from study and experiment and may relate to a process, machine, article of manufacture, composition of matter, or any improvement thereof. An invention may be made by a sole inventor or by more than one inventor. In the legal sense, the inventor must be involved in the conception of the invention.

A patent secures to its owner, who is not necessarily the inventor, the right to take legal action to prevent others from making, using, and selling the invention for a limited period of time. A patent is granted for a term of twenty years from the date on which it is filed. This term can be extended for some pharmaceutical products or processes that are subject to federal regulatory delays.

Conception and Reduction To Practice

The term conception describes the intellectual act of creating a complete inventive concept, and includes methods for making and using the invention. The term reduction to practice is defined either as (a) constructive reduction to practice, which means completing a written, formal description of an invention in a patent application, even though physical embodiment of the invention may not have been realized; or (b) actual reduction to practice, which means making a physical embodiment of an invention and using it successfully for its intended purpose.

Patentable Inventions

As previously mentioned, United States patent law states that patents may be granted on a new and useful process, machine, article of manufacture, composition of matter, or any improvement on these. (A patent may also be granted on a distinct and new variety of plant that is asexually reproduced and any new, original and ornamental design for an article of manufacture.) In addition, patent law also requires an invention to meet the following three criteria:

1. **New or Novel:** The invention must be demonstrably different from any existing prior art. This means it cannot be described in prior public disclosures, which include publications and/or availability of the invention to the public, as in a commercial product.
2. **Useful:** The invention must be useful in ways that represent improvements over existing products and/or techniques.
3. **Nonobvious:** The invention cannot be obvious to a person of "ordinary skill" in the art. Nonobviousness usually is demonstrated by showing that practicing the invention yields surprising, unexpected results.

Each of the previous criteria is open to the judgement and interpretation of the patent examiner, so it is on these several criteria that much of the negotiation between the U.S. Patent Office and the applicant centers. Patent law also requires that inventions be reduced to practice in order to be patentable, but some extrapolation about an inventive concept can be included in a patent application. For example, an invention that claims a broad class of chemical compounds is rarely granted a patent, unless evidence is presented that several different representative members of the class have actually been made. A claim, even to a single new compound or plasmid vector, usually must include a detailed description of its actual synthesis or construction, in order to receive patent protection. Patent protection of novel genes requires the complete sequence and its biological utility.

Record-Keeping

Have a witness sign and date records and explicitly state that the data were observed and understood. The Appendix lists recommended Maintaining complete records of the development of an idea from conception through reduction to practice is an essential step in the formal, legal protection of intellectual property. Records define the invention and establish the dates of its conception and first reduction to practice. They may be needed to prove, for example, that an invention was conceived before a specific publication appeared or a competing invention was made. Laboratory records also may be needed for legal proceedings where issues of definition and legal ownership of intellectual property are to be determined.

The best evidence of conception is a complete and precise description of an invention, including appropriate sketches, and directions on how to make and use it. It is particularly important to include clear, dated statements of the ideas and experiments that led to an invention. These descriptions should be written clearly and in ink.

It is also important to ensure that records are witnessed or corroborated by (four) 4 persons who has the ability to understand the data and the methods used, but who is not a coinventor. At regular intervals, investigators should review the record-keeping procedures:

Effects of Publication on Patent Protection

USUHS investigators are free to publish and present the results of research, subject only to delay for short periods of time required to protect intellectual property.

According to patent law, publication or public disclosure of an invention means the nonconfidential transfer of knowledge--orally or in writing, by exhibits, demonstrations, or public use of the invention- in a manner that would permit others skilled in the art to duplicate the knowledge without undue experimentation. Abstracts, theses, typewritten papers, and slides or projected material as may be distributed or discussed at nonconfidential meetings, conferences, seminars, or forums are examples that may constitute publication or public disclosure.

In the United States, patent applications may be filed up to one year after an invention's first public disclosure. In contrast, most foreign countries require that patent applications be filed before any public disclosure on an invention. Further, because most foreign countries have very broad definitions of public disclosure, even the most casual disclosure of inventions may eliminate the possibility of patent protection. Despite these strict rules, if a U.S. patent application is filed before any publication, most foreign countries permit filing of corresponding applications for up to one year after the U.S. filing date, even if a public disclosure of the invention was made after the U.S. filing. In practice, then, the filing of a U.S. patent application prior to publication preserves both U.S. and foreign patent rights.

Applying for a Patent

Inventions disclosed to CTT will be reviewed and scheduled for a patent search to be made (1) to determine the probability of achieving meaningful patent protection, and (2) to assess the commercial appeal that the invention might have to a company capable of manufacturing and marketing the invention. A literature search, if not already conducted, is requested of the inventors. If a literature search and a patent search fail to find prior art that could render the invention unpatentable, then the invention would be promoted to the private sector in order to identify a potential partner for further development and commercialization. In cases where inventions are judged to be both patentable and commercially attractive, a U.S. patent application will usually be filed. Legal expenses and other fees for such filings are paid by the University or a designated patent management organization. However, reimbursement of costs is sought from research sponsors and licensees.

Review of the Invention Disclosure by CTT, in consultation with the inventor usually takes three to four months or longer. When it is known that the inventor is planning a publication during the near term, the process of reviewing, drafting, and filing a patent application can be accelerated in order to preserve patent rights.

Whether or not an invention has been constructively or actually reduced to practice, the process by which the U.S. Patent Office eventually awards a patent is rarely simple or straightforward. The process usually involves extensive negotiation, much of which centers on whether the invention is nonobvious. The patent application, submitted on behalf of the inventor and the University by patent counsel, consists of

- an abstract;
- the specification (an explanation of the invention's history, described in broad terms that teach the public how to make and use the invention); and
- the claims (precise, numbered statements describing exactly what the inventor claims as the invention).
- Drawing(s) (if necessary to explain the invention)

The U.S. Patent Office issues its first "office action" or reply to the initial patent application in approximately twelve months or longer. This first office action usually rejects most or all of the inventor's claims of invention on the grounds of obviousness; several references (either issued patents or scientific papers) are cited to support the examiner's contention. The inventor and patent attorney then present their case to the patent examiner that the references do not render the invention obvious. Such an exchange continues until a patent is either granted or denied. The entire process may take from two to six years. The cost of a U.S. patent typically ranges from \$15,000 to \$40,000. Foreign patents cost from \$10,000 to \$15,000 per country. Maintenance costs add several thousand dollars per patent.

Biological Materials and Laboratory Techniques

Most biomedical/biotechnological research produces innovations that cannot be easily protected by patents and copyrights. These innovations include such biological materials as clones, plasmids, gene fragments, Special cell lines, DNA probes, hybridomas or monoclonal antibody cell lines, as well as laboratory techniques (know-how).

Patentability

Patent law and the practices of the U.S. Patent Office in the area of biotechnology inventions are evolving gradually. Some biological materials may be patentable as compositions of matter, subject to the general rules of patentability. However, because of the difficulty of describing or defining these materials, it may be desirable or necessary to deposit a culture or specimen in a public depository like the American Type Culture Collection (ATCC). Such a deposit may be required by the U.S. Patent Office, and the deposit must be made as early as the date of filing of the patent application. Deposit may be necessary also to ensure that the materials will be made available to the public as desired by the inventor or as directed by the government agency funding the research.

Protection of Biological (Proprietary) Materials before Distribution

Regardless of the patent status of biological materials and/or know-how, these forms of intellectual property may be scientifically valuable research tools. They may help create links with industry when there is innovative content. Accordingly, it is worthwhile to take the necessary steps to protect these types of intellectual property.

CTT recommends that transfer of all such biological materials of innovative content from USUHS University to an outside party accompany a formal agreement, to be prepared by CTT outlining precise rights granted to the receiving party. An agreement for transmission of biological materials to an investigator in an academic institution for research purposes alone may take the form of a simple Material Transfer Agreement. An agreement with a commercial organization, even if the stated purpose of the transmission is for research only, may require the recipient to enter into a Material License Agreement that often include license fees or royalties. Agreements of these kinds will be prepared and negotiated by CTT.

Laboratory techniques and other forms of know-how are rarely the subject of separate, formal agreements, but provision for their use may be included in licenses or sponsored research agreements. Licenses on know-how typically provide for payment of a royalty, to be paid on sales of products made using the know-how. In situations where know-how may be important to the manufacture and marketing of a commercial product, investigators are encouraged to contact CTT before disclosing such information to a commercial organization.

In order to protect biological materials when distributing them to others, investigators should take the following steps:

- Inform, CTT of the new biological material and determine if the biological material results from an externally sponsored research agreement so that contractual obligations and regulations affecting ownership, disposition of rights, and distribution and use of the biological materials can be determined.
- Inform CTT of the names and addresses of those parties requesting the biological material. It is advised that no commitments be made, whether formal or informal, to supply or maintain specific materials without first consulting CTT?
- CTT shall generate and negotiate the appropriate formal agreements (i.e., material transfer agreements or material license agreements) for distribution of biological materials to parties outside the University. Such agreements generally require users to treat the material as proprietary, and include a statement of ownership and disclaimers of product warranty or liability.
- Under no circumstances should biological materials for evaluation to any users or industry representatives be provided without first labeling the containers or related materials as shown in the sample below.
- Each release of materials shall be documented thoroughly. Record the names and addresses of recipients, and identify the material and date of release. Be sure of the terms of the release. Careful documentation is necessary to demonstrate that no unauthorized, undocumented release of the biological material was made, and that all possible efforts were made by the inventor and the University to protect the material, if commercial distribution is desired in the future.

PROPRIETARY MATERIAL NOTICE

THIS CONTAINS PROPRIETARY MATERIAL THAT IS THE PROPERTY OF (the owners). THIS MATERIAL IS FURNISHED TO ONLY THOSE AUTHORIZED TO USE IT FOR SUCH RESEARCH AS SPECIFIED IN WRITTEN AGREEMENTS. THIS MATERIAL SHALL NOT BE USED, IN WHOLE OR IN PART, WITHOUT TIM WRITTEN PERMISSION OF (the owners).

Copyrights

The University Intellectual Property Committee is reviewing a proposed copyright policy. The draft policy, parallel in structure to the patent policy, provides administrative rules for copyrightable materials. In the interim, CTT considers copyrightable materials inventions on a case-by-case basis when determining ownership and rights. CTT does not routinely seek the registration of copyrights, because generally, the copyright in a work belongs to the work's author. An exception is a work of the United State's Government employee in which, by law (17USC), no copyright can subsist. However, a copyright interest may be assigned to the Government.

A copyrightable work must be an original work, set down in a tangible, or fixed form. Included are traditional written works, and other works such as videotapes, film, music, and paintings. Computer software may be protectable through copyright, as explained below. Copyright is a specific form of intellectual property protection that protects only the expression of an idea, but not the idea itself.

The Copyright Act of 1976 states that an author has statutory copyright protection for a work from the time it is put in a fixed, tangible form. Authors obtain a number of exclusive rights under copyright protection:

the right to reproduce the work;
the right to prepare derivative works based on the original;
the right to distribute copies to the public;
the right to perform the work publicly; and
the right to display the work publicly

For works owned by the original authors, copyright extends for the author's life plus 50 years. When the author is an employer rather than the individual(s) who prepared the work (a "work for hire"), copyright extends from the earlier of 75 years from the date of publication or 100 years from the time the work was created. Under the two major concepts of **fair use** and **library reproduction rights**, the 1976 Copyright Act gives the general public the right to make very specific limited use of copyrighted works usually for educational purposes, at no cost and without permission of the authors.

Copyright Notice

The copyright notice attached to a work intended for publication, includes the name of the copyright owner, the year in which the work is published and the copyright symbol:

© 1999 Lee G. Author

or

© 1999 USUHS University

The year given in the copyright notice should not be updated each time the work is printed, copied or published.

Changes in the Copyright Statute

On March 1, 1989, major changes in the copyright statute became effective. The United States became a member of the Berne Convention for the Protection of Literary and Artistic Works, which is considered to be the best of the international treaties for the protection of copyrights.

One important change is that the copyright notice is no longer required for works published after March 1, 1989. All works published for the first time after that date may be assumed to be automatically copyright-protected, even though no copyright notice appears.

Even though the notice is not required, CTT strongly recommends use of the copyright notice as well as prompt registration in the Copyright Office of all published works of any substantial value. These actions offer a number of advantages for the author: the document is retained; the work is protected in countries that belong to the Universal Copyright Convention but not to the Berne Convention; the copyright can be more effectively enforced against infringers; and the author is in a better position to prove infringement.

The concept of fair use states that in specific and limited circumstances, portions of copyrighted works may be copied for such purposes as criticism, comment, teaching, and research without infringing the copyright.

Computer Software

The term computer software is used to designate computer programs, in the broadest sense, and is meant to include users' manuals and other explanatory material that accompany computer programs, and computerized databases. Also included are microcodes, subroutines, operating systems, high-level languages, application programs in whatever form expressed (machine or assembly language, source or object code) or embodied (chip architecture, CD-ROM, disk or tape storage, program listings).

The primary goals in protecting and managing software are to promote the widest possible distribution for the benefit of the public, and to produce revenue for the author of the software and the department. There are two basic **approaches to** distribution:

- the author or the department can distribute directly to users for a fee or at cost, or
- the author, or in some cases the University, can make, a distribution agreement with a commercial entity

Although some software can be copyrighted and/or patented, the statutory situation surrounding its protection is confusing and constantly changing. Accordingly, authors should be especially careful in protecting and distributing software. Some starting points and tasks to consider in protecting and disseminating software are the determination of

- ownership;
- best method for broad distribution of the software (for a fee or at cost directly by the author's laboratory, or through an agreement with a commercial organization); and
- disposition of income resulting from distribution.

Whether or not commercial distribution of software is anticipated, it is important to protect software so that the author or University will be able to control and facilitate distribution, insure the integrity of the work, and protect the rights of the authors.

Under current U.S. law, not all computer software may be patentable. It is, however, covered by the Copyright Act of 1976, under which computer software (as well as all other copyrightable work) is protected by federal statute from the moment it is "fixed" in a tangible form.

Copyrighting Software

The steps for obtaining copyright protection for computer software are the same as those for other copyrightable works. However, the option to formally register the software, is ordinarily not pursued. Registration requires deposit of copies of the work with the Copyright Office in Washington, D.C. Such deposit of unpublished software may serve to make the work more easily accessible to nonauthorized user's who, by making slight changes, may create a "new work." Under the present law, it is possible that this "new work", may not can be considered an infringement of the original. Copyright protection can be claimed without registration or the deposit of copies with the copyright of Registration is primarily useful if litigation occurs. Works can be registered at the time a suit is brought.

Although it is important to claim copyright protection, copyright alone is not always adequate protection for software., Copyright law protects the form in which ideas are expressed, not the ideas themselves. As a consequence, elements of software can sometimes be utilized without infringing the copyright in the software. From a commercial point of view, copyright protection for software is frequently inadequate.

Software As Proprietary Information

The limited protection offered by copyright law can be enhanced by designating software as "proprietary information" and requiring users to treat it as such. Treating it in this way demonstrates the author's view that the intellectual property is valuable and should be protected against potential infringers. In addition, establishing a proprietary position is crucial to attracting outside organizations capable of distributing the software. Generally, commercial distributors will not undertake marketing efforts unless software has been protected as fully as possible from the start both by copyright and the requirement that users treat the software as proprietary information. The requirement that software be treated as proprietary information would apply to the software and accompanying materials only (e.g., programs and manuals) that are readily usable by others, and not on the basic scientific concepts upon which the software is based. In keeping with the University's educational and scholarly purposes, such basic concepts should be openly available through publication or other means.

Distributing Software

When distributing software, authors should take the following protective steps:

- Inform CTT if the author wishes to determine if copyright protection of the software is available before distributing it to users.
- Consult with CTT, if the software results from an externally sponsored research agreement so that contractual obligations and regulations affecting ownership, disposition of rights, and distribution and use of the software can be determined.
- Make certain that the appropriate copyright notice is prominently displayed on the work, that is, on all displays of the programs as well as on all tapes, disks, manuals, and associated materials.
- Do not release software for loan, review, sale, lease, in-house use, or other purposes without first having fixed one of the sample labels shown below to the tapes, disks, manuals, or to other components of the software

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When software has potential commercial value as well as academic or research value, the following additional steps can be taken:

- Use letter agreements for distribution to users, inside or outside the University, who want to use the software for research purposes only. Examples of such letters can be supplied upon request to CTT.
- In general, do not make commitments to install, service, or maintain software in any licenses or other distribution agreements, whether formal or informal.
- When income is anticipated, consult with CTT for advice on its disposition.
- Document each release thoroughly by recording addresses of recipients, number of copies and date of release. It is important that copies of all letters or other agreements stating the terms of release are retained. Thorough documentation will demonstrate that no unauthorized, undocumented release of the software was made, and that all possible efforts were made to protect it, in the event future commercial distribution is desired, or defense against infringement becomes necessary.

Licensing And Other Agreements With Industry

Formal University-industry agreements which may be handled or reviewed by CTT are of the following kinds:

- Licensing Agreements
- Material Transfer Agreements
- Confidentiality Agreements
- Research Agreements
- Cooperative Research and Development Agreements (CRADA)
- Patent Cost-Sharing Agreements

Technology Licenses

Once an invention has been made and disclosed, CTT with the aid of the inventor can begin seeking potential licensees. In cases where discussions with industry representatives are necessary before a patent application can be filed, potential licensees often receive the technical details of an invention under a confidentiality agreement, which is executed by CTT. A license is an agreement under which the licensor (USUHS University) grants a licensee (the company) the right to make, use and sell products based on the licensed invention. In licensing an invention, CTT has several options. These include licensing exclusively or nonexclusively. The license agreement may be based on patent rights, biological material, know-how, and/or technical material.

Licenses may extend for a few years or for the life of patents. Important license provisions include the University's right to take back the technology if the licensee is not aggressively pursuing its development; financial terms including an execution license fee (or "up-front" payment); minimum, annual royalties; and royalties on net sales of products. Occasionally, a company will want a short-term, exclusive option for a license while either it or the inventor conducts further tests of an invention's efficacy. Success of a license agreement depends on both parties satisfying some basic goals. For example, the inventor and the University must be assured that the technology will be diligently developed for public use, and it will receive an equitable share of the financial rewards resulting from the invention's commercialization. The licensee, in turn, must have sufficient rights to develop a product that will be profitable for a certain period of time. License agreements are, negotiated and maintained by CTT.

Research Agreements

Industry-sponsored research agreements are grants or contracts that fund research. In most cases these agreements represent a commitment by both parties to collaborate in investigating an area of mutual scientific interest. As with any agreement, terms and conditions must satisfy the basic goals of both parties. The University must be sure that the funds are used to support appropriate academic research activities. The industry sponsor must be sure that it funds research in an area of both scientific and commercial interest; the resulting intellectual property must be carefully and effectively protected; and the sponsor must have rights to such property. Research agreements are executed by the President (USUHS). CTT provides the review and negotiation of the protection of intellectual property, invention rights, and options to licenses for inventions.

Letter Agreements

Letter agreements are short contracts or grants, informal in comparison with licenses and research agreements, which are used generally when distributing biological materials or other laboratory materials to scientists at other academic institutions or in business. Samples of letter agreements are available at CTT.

Negotiation of Agreements

Although each industrial agreement is unique, there are common steps in every negotiation. The process begins with exploratory discussions between USUHS investigators and CTT licensing professionals and representatives of a potential licensee or industry research sponsor. The purpose of these meetings is to evaluate common interests and determine if a basis for a relationship exists. It is important that the respective parties are represented by at least one person who is authorized to make binding commitments for their organization. Otherwise, negotiations can easily become over-extended and may end without constructive result. Clear definitions of innovative ideas and the goals of the parties are crucial, if discussions are to proceed. Initial discussions are typically conducted without formal written proposals on the table.

The second step in the process is agreement. In principle that the innovative ideas and the shared goals of the parties are sufficient to form the basis for a formal agreement. The third step consists of negotiations between the parties, which shall not include the University inventor, aimed at reaching a formal agreement. Whether the proposed agreement establishes a license to a USUHS invention or initiates sponsored research, negotiations focus on the following issues: term of the agreement, exclusively or nonexclusively, field of use, ownership, compensation (such as royalties, license fees, research budget), publication, confidentiality of information, and provisions for indemnification, warranty, infringement, termination, and extension. The final step in the negotiation process is execution of the agreement by the parties concerned.

The entire process can take a few months or a year or more. Patience and perspective are essential to working successfully through all of these steps. Once agreements are fully negotiated, the institutions and individuals involved can work toward the common goal of developing important and beneficial technologies for public use, and receive the recognition and compensation that is due when the technology is successfully developed and marketed.

Center For Technology Transfer (CTT)
(October, 1999)